EXHIBIT S

Footnote 31

"Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System?"

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Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System?

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"Patterns of adverse events, or an unusually high number of adverse events reported after a particular vaccine, are called 'signals.' If a signal is identified through VAERS, scientist[s] may conduct further studies to find out if the signal represents an actual risk."

CDC on Vaccine Safety

Abstract

Following the initiation of the global rollout and administration of the COVID-19 vaccines[1,2] on December 17, 2020, in the United States, hundreds of thousands of individuals have reported Adverse Events (AEs) using the Vaccine Adverse Events Reports System (VAERS). To date, approximately 50% of the population of the United States have received 2 doses of the COVID-19 products with 427,831 AEs reported into VAERS as of August 6th, 2021.

Pharmacovigilance (PV) is the process of collecting, monitoring, and evaluating AEs for safety signals to reduce harm to the public in the context of pharmaceutical and biological agents. Many of the issues with VAERS are becoming well known – especially with regards to reporting and recording of data – in light of the extensive use of this system this year, challenging its functionality as a pharmacovigilance system.

This appraisal assesses three issues that respond to the question of VAERS pharmacovigilance by analyzing VAERS data: 1. deleted reports, 2. delayed entry of reports and 3. recoding of Medical Dictionary for Regulatory Activities (MedDRA) terms from severe to mild. The most recently updated publicly available VAERS dataset was found to have N=1516 (0.4%) VAERS IDs removed ("missing").

1 The Brand Name: Pfizer-BioNTech COVID-19 Vaccine, the Previous Name: BNT162b2 or the Company Name: Pfizer Inc. and BioNTech SE. can be used in the case of the Pfizer/BioNTech COVID-19 products. The Brand Name: mRNA-1273 and/or Company Name: Moderna, Inc. can be used in the case of the Moderna COVID-19 products.

2 mRNA biologicals are not true vaccines. True vaccines undergo time-dependent testing protocols to ensure safety and efficacy, typically enduring between 10 and 15 years. True vaccines are a preparation of a weakened or killed pathogen, such as a bacterium or virus, or of a portion of the pathogen's structure that, upon administration to an individual, stimulates antibody production or cellular immunity against the pathogen but is incapable of causing severe infection. The mRNA biologicals do not satisfy either these requirements and as such are more akin to experimental treatments than vaccines.

Of this missing data, 13% represented death, 11% represented COVID-19 and 63% represented Severe Adverse Events (SAEs). Of these missing death data, only 59% represented redundancies – re-assigned new VAERS IDs – the remainder were unaccounted for.

A lag time between onset of AEs and entry of AEs into the VAERS public database was discovered, and it appears to depend on the AE type. For example, in the case of COVID-19 breakthrough cases, approximately mid-May, 4100 (38% of total) reports were retroactively added approximately 8.5 weeks following the original onset date. SAEs were not found to be downgraded to mild AEs (MAEs) for a tested cohort within 10 selected updates.

VAERS is designed to reveal potential early-warning risk signals from data, but if these signals are not detectable as they are received, then they are not useful as warnings. Considering the relevance of safety concerns in the face of the large numbers of AEs being reported into the VAERS system in the context of COVID-19 products, it is essential that the VAERS system be carefully and meticulously maintained. Despite the emergence of the Standard Operating Procedures (SOP) for COVID-19, VAERS is lacking in transparency and efficiency as a PV system, and it requires amendment or replacement.

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Keywords
COVID-19; Vaccine Adverse Events Reports System (VAERS); Adverse Events (AEs); Severe Adverse Events (SAEs); Mild Adverse Events (MAEs); VAERS Wayback Machine; Standard Operating Procedures (SOP); Medical Dictionary for Regulatory Activities (MedDRA); Pharmacovigilance (PV)

Contents

1 Background

Pharmacovigilance is the process of collecting, monitoring, and evaluating AEs for safety signals to reduce harm and promote safety to the public in the context of pharmaceutical and biological agents [1,2]. There are a number of organizations and agencies that exist to ensure pharmacovigilance as part of regulation of biological products from conception to administration into humans for use. The Center for Biologics Evaluation and Research (CBER), as an example, actively participates in international pharmacovigilance efforts under the umbrella of the Food and Drug Administration (FDA) and the Department of Human Health Services (DHHS) [3]. International regulatory organizations such as the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the World Intellectual Property Organization (WIPO) also function to ensure pharmacovigilance in biologicals and serve as sources of guidance pertaining to pharmacovigilance efforts. In addition, individual countries have their own regulatory authorities, such as the Medicines & Healthcare products Regulatory Agency (MHRA) of the United Kingdom (U.K.), responsible for rule and regulation enforcement and the issuance of guidelines to ensure pharmacovigilance in the development and administration of biological products. The U.K. 'Coronavirus Yellow

Card' reporting site allows collection of AE data monitored by the MHRA.

The U.S. FDA and Centers for Disease Control and Prevention (CDC) created and implemented the Vaccine Adverse Event Reporting System (VAERS) in 1990 to receive reports about AEs that may be associated with biological products such as vaccines.[3] Most vaccine AE reports in VAERS concern relatively minor events, such as injection site pain. Other reports describe serious events, such as hospitalizations, life-threatening illnesses, or deaths [4,5,6,7,8]. The reports of serious events are of greatest concern and are meant to receive the most scrutiny by VAERS staff and healthcare professionals. The primary purpose of the database is as a pharmacovigilance tool – to serve as an early warning or signaling system for AEs not detected during pre-market testing. The National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine manufacturers to report AEs to the DHHS following the administration of vaccines outlined in the Act [4,5,6,7]. Reported AEs, as part of the VAERS system, represent a fraction of the actual number of AE incidents, so the numbers reported herein are likely far lower than actual numbers [6,7,9]. VAERS reports can be made by nurse practitioners, general practitioners, or family members, which can result in duplicate reports being made. As part of the VAERS Standard Operating Procedures for COVID-19 (SOP)[4] published on January 29th, 2021, the CDC and the FDA are meant to perform routine VAERS surveillance to identify potential emergent safety concerns in the context of COVID-19 injectable products [5,6,7,10,11,12]. Accordingly, VAERS reports are received, processed, and managed by trained CDC contractors. The VAERS reports are received online for subsequent review, and symptoms and diagnoses are assigned MedDRA standard codes. Additional information, including hospital records and autopsy reports, will be requested by these trained staff when appropriate, as outlined in the SOP. Reports are often changed or deleted. For example, in the case where a person successfully files a report using the VAERS system and subsequently dies, they are, in some cases, assigned a new VAERS ID number, unlinking their reported AEs and death records. In addition, as the AEs may become more enumerable in an individual, multiple changes can be made to their VAERS report under the same VAERS ID number or, as indicated, under a different VAERS ID number if they die.

An Adverse Event (AE) is defined as any untoward or unfavorable medical occurrence in a human study participant, including any abnormal physical exam or laboratory finding, symptom, or disease temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research. Based on the Code of Federal Regulations, a Serious or Severe Adverse Event (SAE)[5] is defined as any adverse event that results in death, is life threatening, or places the participant at immediate risk of death from the event as it occurred, requires or prolongs hospitalization, causes persistent or significant disability or incapacity, results in congenital anomalies or birth defects, or is another

3 VAERS has benefits of the PREP Act – while vaccine manufacturers are shielded from liability, and vaccine proponents tout VAERS as an example of active PV, VAERS users must acknowledge the data cannot be used to establish causality.

4 Vaccine Adverse Event Reporting System (VAERS), Standard Operating Procedures for COVID-19 (as of 29 January 2021), VAERS Team: Immunization Safety Office, Division of Healthcare Quality Promotion National Center for Emerging and Zoonotic Infectious Diseases and Centers for Disease Control and Prevention.

5 NIA Adverse Event and Serious Adverse Event Guidelines (2018). https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf

condition which investigators judge to represent significant hazards.[6] The VAERS handbook states that approximately 15% of reported AEs are classified as severe [4]. Nowhere in the VAERS handbook or on the website published by the CDC/FDA is there mention of deleted data or transparent description of the processes and criteria used for record deletion. The only reference I could find to legitimate removal of data, from WONDER's 'Reporting Issues' section, claims that 'Duplicate event reports and/or reports determined to be false are removed from VAERS'.[7]

A Wayback Machine[8] is an initiative of the Internet Archive, a 501(c)(3) non-profit, building a digital library of Internet sites and other cultural artifacts in digital form. The VAERS Wayback Machine[9] therefore allows an examination of the VAERS government data input each week. The U.S. Government publishes a new version of its VAERS database weekly and VAERS IDs can be changed or even deleted without documentation of edits. The VAERS Wayback Machine provides a way to trace and track deleted files based on matches in field entries between VAERS ID versions.[10]

2 Methods

General methodology and descriptive statistics

To analyze the VAERS data sets, R was used. (R: a language and environment for statistical computing.) VAERS data are accessed through the CDC Wide-ranging Online Data for Epidemiologic Research (WONDER) system. The VAERS data are available for download[11] in three separate comma-separated values (csv) files representing (i) general data for each report; (ii) the reported AEs or 'symptoms'; and (iii) vaccine data for each report, including vaccine manufacturer and lot number. The VAERS dataset is updated weekly. Upon individual reporting of vaccine side effects or AEs, a VAERS ID number is provided to the individual to preserve confidentiality, and a detailed description of the AEs are transcribed along with the individual's age, residence by state, past medical history, allergies and gender, and many other details. In addition, the vaccine lot number, place of vaccination and manufacturer details are included in the report.

The VAERS ID was used as a linking variable to merge the three csv files. Data was filtered according to vaccine type (reports made only for COVID-19), and all variables were retained, including VAERS ID, AEs, age, gender, state, vaccination date, date of death, incident of death, dose series, treatment lot number, treatment manufacturer, hospitalizations, emergency department visits, disabilities, life threatening AEs, birth defects and onset date of AEs. Deaths are categorized according to whether or not the individual had been marked as 'DIED'. Erroneous labelling is an issue in VAERS, for example, when 'Death' is an AE and yet the 'DIED' column is marked 'NA' or 'not applicable', thus the dataframe was checked and corrected for inconsistencies in the 'DIED' column vector. For the purposes of this analysis, deaths according to VAERS classification by 'DIED' plus these corrected cases of misclassification are reported here and used in the analysis. The grouped AE categories hospitalizations and emergency doctor visits were created by

6 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?
7 VAERS data can be accessed through the CDC Wide-ranging Online Data for Epidemiologic Research (WONDER) system. https://wonder.cdc.gov/vaers.html
8 https://web.archive.org/
9 https://medalerts.org/vaersdb/wayback/
10 https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html
11 https://vaers.hhs.gov/data/datasets

selecting 'Y' in the respective column vectors, while the cardiovascular, neurological and immunological groups were created by selecting keywords indicative of a respective medical issue. The SAEs were classified according to whether the individual succumbed to death, was hospitalized, was admitted to the ER, experienced a disability or a life-threatening AE, or if a birth defect ensued.

It should be noted at this point that anyone using the VAERS WONDER system will not see the same counts that are described in this analysis, since hospitalizations, ER visits and all SAEs counts were calculated by counting the 'Y' entries in the respective fields in the merged file. The difference between the counts in this analysis and counts from a WONDER query are simply due to the effect of losing field entries by merging the files. If one uses the files available for download from the VAERS website with the aim of comprehensive analysis of the full range of data, the 3 csv files must be merged. In order to know what 'SYMPTOMS' an individual succumbed to prior to death, for example, or to know what injectable product they were given, it is necessary to merge the DATA file with the SYMPTOM file and the VAX file. It is also vital to omit redundancies in VAERS IDs – if not done, this could lead to excess numbers in absolute counts. The downside to the merge is loss of data due to incomplete field entries; however, it is important to note that the merge counts are under-approximations, yet still prove the points made herein.

Deleted data were isolated and aggregated by using anti-join iterations in R on sequential dataframes. Anti-join returns the rows of the first dataframe that are not matched in a second dataframe. This was done iteratively for all sequential dataframes, and the unmatched data were aggregated and put into a new file entitled 'missing data'. The collective missing data file was subsequently filtered for duplicates to ensure that redundancies were omitted.

A missing VAERS ID can be missing due to having been removed because it is redundant, or for reasons yet unknown. The former entries are re-assigned a new VAERS ID and are traceable by matching fields in column vectors of dataframes. The latter are missing due to unknown reasons. To discern between redundant and deleted VAERS IDs, deleted data were cross-referenced by matching fields for relevant selected variables in the most recently updated publicly available dataset. This was done only for the deleted death data, since it is a time-consuming exercise. The matching algorithm was as follows: match age, state, and gender followed by vaccine lot if available, onset, vaccine and death dates followed by allergies, medications, and any other unique identifiers of the individual. If a match was found, the newly assigned VAERS ID was recorded alongside the old VAERS ID in a new file. If a match was not found, then the VAERS ID was deemed to have been deleted from the database.

Two methods were used to investigate temporal lags in data entry. The first method involved using only the most recently updated publicly available dataset. Assessment of temporal differences in data entry was done by calculating the difference in the number of days between the onset date (ONSET_DATE)[12] and the date that the AE was entered into the VAERS database (TODAY'S_DATE).[13] The second method involved comparing the data from the weekly updates to the most recently updated file. Each week, a new set of data is available for download from the VAERS website, as mentioned previously. As an example of how the data sets were compared, consider the first and the last VAERS datasets available for download in

12 Onset Date (ONSET_DATE): The date of the onset of adverse event symptoms associated with the vaccination as recorded in the specified field of the form.

13 Today's date (TODAYS_DATE): Date Form Completed.

2021. According to a reference variable, such as the ONSET_DATE, these two datasets should both and equally capture all AEs submitted to VAERS from January 1st through January 7th, 2021, since the first available dataset would comprise the first week of data. If any two datasets do not equally capture all AEs, then this discrepancy would warrant explanation. A feasible explanation for a non-match in the number of VAERS IDs per ONSET_DATE entries reported would be retroactive addition of reports to the system due to a backlog.

The incidence of SAE downgrade to MAE was assessed by choosing 10 update files, calculating the SAE and MAEs, and subsequently comparing them to original counts for SAE and MAE in the original files. This was done using the semi-join function in R.

Statistical Testing

Statistical analysis was done using the Student's t-Test to determine statistically significant differences between AE types in the deleted data file. Skewing in distribution of data was tested using Pearson's Skewness Index, I, which is defined as I = (mean-mode)/standard deviation. The data set is considered to be significantly skewed if $|I| \geq 1$.

3 Results

3.1 Historical pharmacovigilance of VAERS and other safety monitoring systems

VAERS and other safety monitoring systems have been useful for pharmacovigilance in the past. In 2010, rotavirus vaccines licensed in the U.S were found to contain Porcine circovirus (PCV) type 1 and were subsequently suspended. On 22 March, 2010, the FDA issued a statement recommending that clinicians and public health professionals in the United States temporarily suspend the use of Rotarix [13,14,15]. In 2009, an increased risk of narcolepsy was found following vaccination with a monovalent H1N1 influenza vaccine that was used in several European countries during the H1N1 influenza pandemic [15,16,17]. Between 2005 and 2008, a meningococcal vaccine was suspected to cause Guillain-Barré Syndrome (GBS) [15,18]. In 1998, a vaccine designed to prevent rotavirus gastroenteritis was associated with childhood intussusception after being vaccinated [15,19–29]. Also in 1998, a hepatitis B vaccine product was linked to multiple sclerosis (MS) [15,30]. Pharmacovigilance has functioned in the context of COVID-19 VAERS data with regards to myocarditis, resulting in a COVID-19 vaccine safety update by the Advisory Committee on Immunization Practices (ACIP, June 23rd, 2021) by Tom Shimabukuro. The report did not result in any changes to the rollout despite the danger signal having arisen [31].

To date, 50% of the total US population has received 2 doses of COVID-19 products,[14] with 427,831 AEs reported as of August 6th, 2021. These numbers are off the scale with regards to numbers associated with vaccine rollouts when compared to previous years. Even more atypical are the numbers of deaths reported in the context of the COVID-19 products. Figure 1 shows the total VAERS reports from data and total VAERS-reported death counts per year for the past 10 years up to and including the VAERS update on August 6th, 2021. Both the absolute numbers of total AEs and those of deaths per year dramatically outnumber the absolute numbers recorded in previous years. To date, there are 6639 (1.6% of all AEs) deaths in the VAERS database. Normalization to fully injected populations were done and compared with INFLUENZA vaccine data for past years and it was

14 https://usafacts.org/visualizations/covid-vaccine-tracker-states/

Figure 1: Bar plots showing the number of VAERS reports (left) and reported deaths (right) per year for the past decade. (2021 is partial data set.)

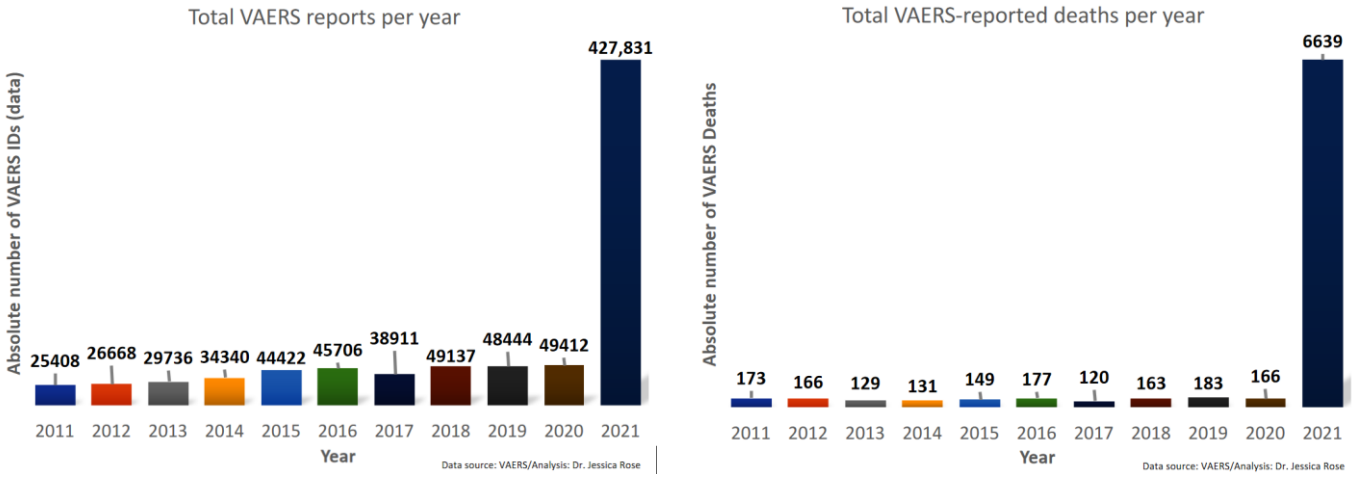
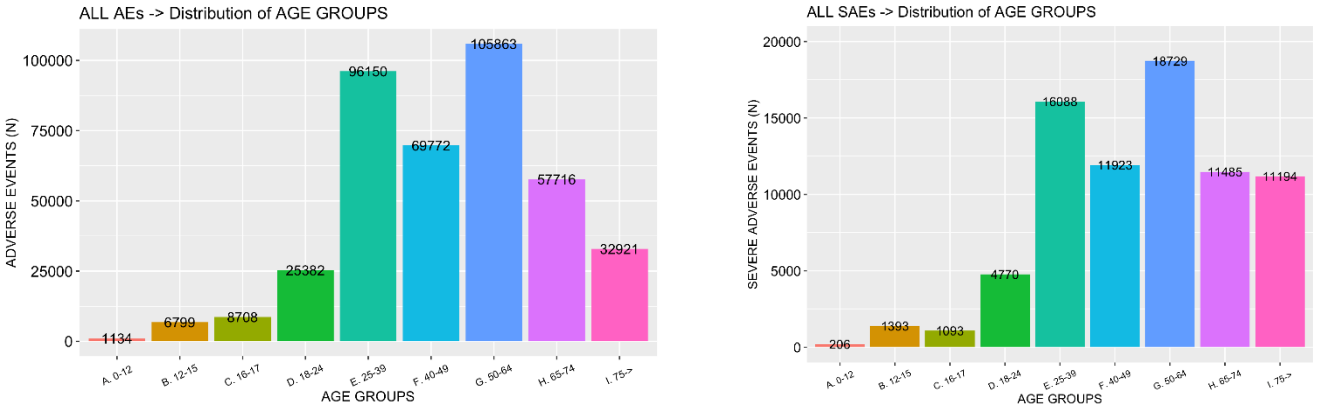


Figure 2: Histogram plots showing distributions of the AEs of the total VAERS ID count (left) and for SAEs (right).



found that the increase in AEs is not due simply due to an increase in injections [32].

As part of an ongoing analysis [8], VAERS data are being monitored according to weekly updates. Figure 2 shows the total AE count (up to and including the August 6th, 2021, VAERS update) by age group alongside the SAE data by age group (according to CDC age group classifications). The distribution in both cases is symmetric and unimodal, not skewed toward any particular age group, potentially meaning that there is no particular age group with lesser chance of succumbing to an AE or, more importantly, an SAE. Of the SAEs, there are 6,639 deaths, 26,402 hospitalizations, 59,061 ER visits, 7,423 life-threatening events, 6,861 disabled and 258 birth defects reported.

Female reproductive issues (FRIs) and AEs in children aged 12–18 years are on the rise. There are currently 6,398 total FRIs and 18,021 AEs reported in young children aged 12 through 18. These children represent 4.2% of the total VAERS data and 12.9% of all cardiovascular AEs. It should be highlighted that the rollout has only just begun recently for children in these young demographics. Figure 3 shows histograms for the FRIs (left) and

Figure 3: Histogram plots showing the distributions of female reproductive issue AEs and AEs in children aged 12–18 years old from the VAERS dataset according to age group (left) and age in years (right).

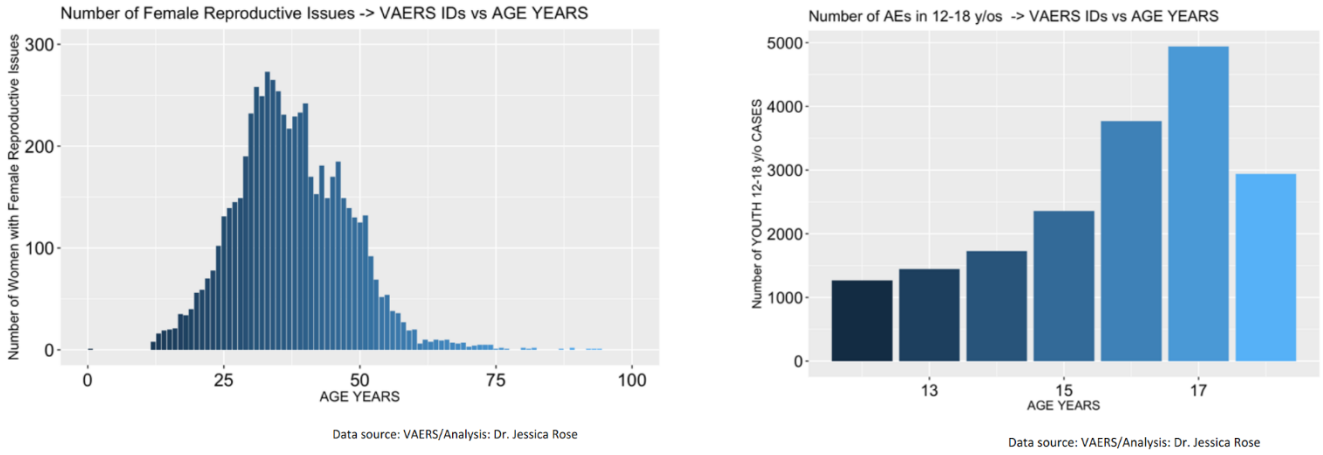
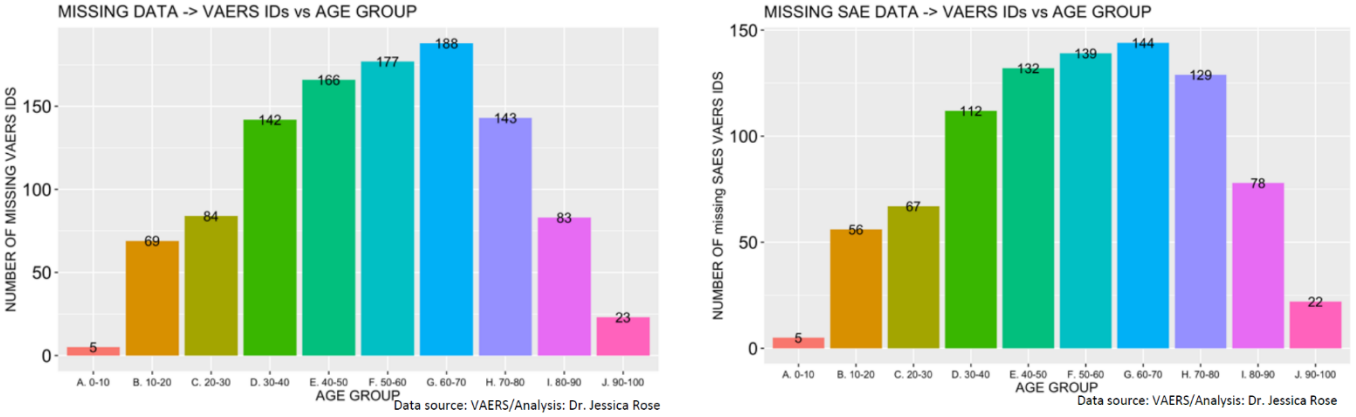


Figure 4: Histogram plots showing the distributions of the missing data of the total AE counts (left) and for SAEs (right) from the VAERS dataset according to age group.



for the children (right) with respect to age in years. Most reports within the children aged 12–18 were made for 17-year-olds.

3.2 Missing data

To date (August 6th, 2021), 1,516 VAERS IDs are missing from the most recently updated publicly available VAERS database. This represents 0.4% of the total VAERS IDs. For each of the 28 updates, one anti-join iteration was performed between sequential updates. For each anti-join iteration, of which there are currently 27, the extracted missing data counts are as follows: 10, 13, 20, 20, 4, 12, 30, 18, 41, 14, 25, 24, 45, 72, 89, 77, 69, 102, 53, 115, 89, 167, 95, 63, 62, 87 and 101. That is, between the first update and the second, 10 VAERS IDs are missing; between the second and third, 13 VAERS IDs are missing, and so on up to the second-last and the most recent update where 101 VAERS IDs are missing. Figure 4 shows the distribution of the missing data according to age groups for the entire missing data set (left) and for the SAEs within the set (right). The missing data are distributed in a symmetric and unimodal way with regards to age groups and are not skewed toward any group in a statistically significant way (I=-0.2) when compared to the dataset without removals.

Interestingly, when the data are not filtered by age group, 63% of all missing data reports qualify

as Severe AEs, and this represents 1.2% of the total SAEs reported to VAERS. When the data are filtered by age group, this percentage becomes 81%, as shown in Figure 4. The missing SAE data are distributed in a symmetric and unimodal way with regards to age groups and are not skewed toward any group in a statistically significant way (I=-0.4).

Of the total missing VAERS ID data set, 41% of the missing IDs involved hospitalizations and 37% involved emergency room visits (data not shown). Histograms of these two categories do not show any statistically significant skewing toward any particular age group (I=0.1 and I=-0.1, respectively; not shown).

Individuals who succumb to and are diagnosed with COVID-19 post-injection, also known as breakthrough events, comprise 11% of the total missing data (1.4% of total VAERS IDs). It is very strange to report that 70% of the age data contains an "NA" entry in the "AGE_YRS" field and thus age-grouped data analysis is not tenable here. FRIs comprise 0.8% of the missing VAERS IDs (0.2% of total FRIs reported to VAERS).

3.2.1 Death data comprises 13% of missing data

Although the absolute number of missing VAERS IDs may not be high, of this small subset of deleted data, 13% of total missing AEs are deaths. The total number of deaths is 199 and in each sequential iteration of the anti-joining of the datasets, death remained at the highest or near highest frequency for missing AEs in each "SYMPTOM" list for the extracted missing data set, save for SYMPTOM column 5, which rarely contains the primary or most prevalent AE reported per individual. For example, of the 5 SYMPTOM column variables representative of the reported AEs, SYMPTOM column 1 primarily contains the most prevalent AE listed and has 'COVID-19' as the #1 most frequently occurring missing report (22%) with 'Death' at #2 (15%). This missing death data comprises 3% of the total VAERS death reports.

Figure 5: A histogram plot showing distribution of missing death data according to age group

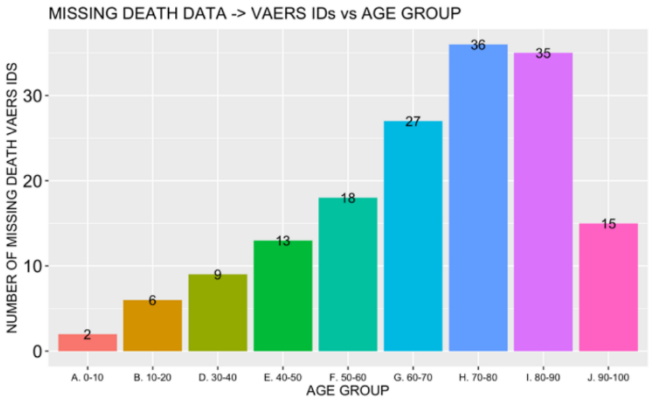
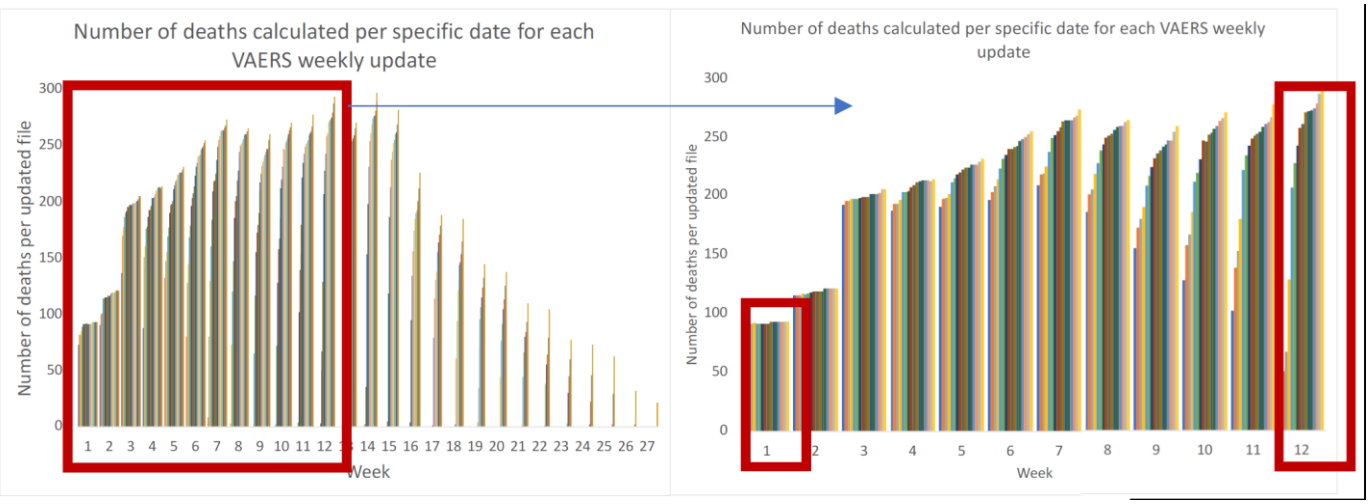


Figure 5 shows that the distribution of deleted death data is asymmetric, unimodal and not skewed in a statistically significantly way toward any specific age group in this data set (Figure 7 (I)=0.7). Of the missing death data, 15% of reports were made within 24 hours and 28% of reports were made within 48 hours indicating a clustering of reports in very close temporal proximity to the injection.

3.3 Redundancy deletions versus deletions for unknown reasons in death reports

There are 199 deleted death entries to date from the VAERS database and 214 deleted death entries to date collected from the VAERS Wayback Machine. The discrepancy of 15 deleted deaths, which accounts for 3% of all reported deaths, arises from deletions of individuals in a 'foreign location' that are not included on the publicly available Domestic dataset. The deleted death data list can be found in the Supplementary materials. Deletions of redundant entries are marked by NA in the 'True deletions' column and the accompanying new VAERS IDs are listed. Deletions due to unknown reasons are marked by TRUE value in the 'True deletions' column. Of the total list, 59% were found to be redundant entries and 41% of the entries were true deletions. For the remaining 1317 non-death-related AEs, a cross-reference search would need to

Figure 6: Bar plots showing the discrepancies in cumulative data by slope of increase at the beginning of the data versus slope of decrease at the end (current update)



be completed in future work to discover what percentage of total missing AEs are true deletions.

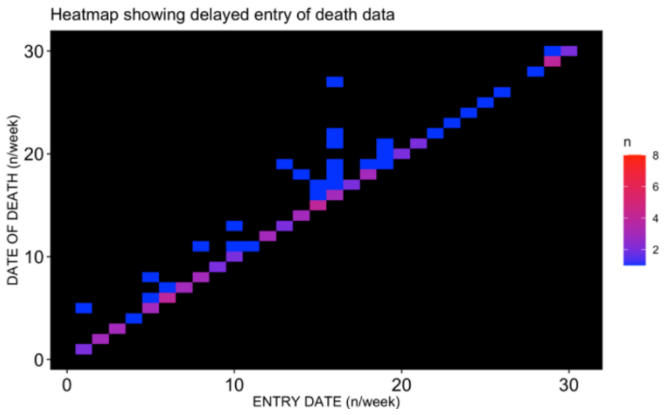
3.4 Unexplained lag in data input

An anomaly in the data pertaining to data entry times when compared to onset of AE dates can be seen when total AE counts reported in the most recently updated publicly-available VAERS dataset (updated August 6th, 2021) are compared with total AE counts as per VAERS weekly updates. To date, there are 28 sets of data, and discrepancies can be found between the files from update to update. This would not necessarily be perceived by a data analyst if they were simply looking at the data from the most recently uploaded data to the VAERS system. One would only notice this discrepancy if simultaneously analyzing the individual sets as compared with the most recently updated set by update date. If the VAERS system was functioning as a pharmacovigilance system and in fact passive, these data sets would be expected to follow the same trajectory. Evidently, there are two trajectories, and they are not similar quantitatively or qualitatively.

Figure 6 (left) shows the number of deaths for each specific update date per week. For example, the first row of bars with x-axis marker '1' shows the number of deaths for each of the updates according to weeks 1–27 (01/30/21–07/30/21). A closer look (examining only weeks 1–12 for clarity) at Figure 6 (right) reveals that the number of deaths were essentially equal for the first 12 updates for week 1. By week 12, this number started to change with respect to week-by-week calculations of death counts. If we observe the slope of the difference in absolute number in the data per update date, it is increasing quite consistently as the week number increases. This is precisely what we would expect to see if data were being retroactively added. The inconsistency is the increasing slope that emerges. It should not be increasing – not even remotely. The only increase we would expect to see is a grouped increase over a week. Absolute numbers should not change per week with respect to weekly data already entered. Thus, if data are being retroactively added, then we would see changes reflected per week as shown in the red rectangle on the right in Figure 6 (right).

Another way to visualize this phenomenon is using a heatmap. Figure 7 is a correlation plot illustrating the number of deaths per week for death week versus the week of entry into the VAERS

Figure 7: Heatmap showing the delayed death data entries where n is the number of deaths per intersection tile



database. Any entry that is not on the diagonal is an entry that was not entered on the week that the person died. 21 tiles (42%) representing n>1 deaths indicates that many entries were entered well after the death date. In one case, the AE was entered 77 days post death. This is clear evidence of death data being retroactively added. Considering that death certificates can take time to be processed, it is to be expected that some death entries to VAERS would occur quite temporally distal to the date of death, but this is a phenomenon that was observed for any AE checked.

3.4.1 Why does this matter?

This corroborates the hypothesis that there is a lag-phase between reporting and recording of data. The duration between reporting following onset of an AE reaction and recording into the VAERS publicly available data varies from a few days to many months. Figure 8 shows the difference in data with respect to the data as per weekly update and to the updated data as of August 6th, 2021, for all SAEs. The black shaded area represents data that is in excess with regards to the data originally presented to the public. The data under the blue line is the most recently update data and the data under the red line is the weekly updated data. The most alarming observation from this figure, however, is the amount of data that was present early on that simply was not publicly available at the time that they were generated. For example, the Δ cumulative AEs between the individual updated data for week 10 is 19,536. The Δ time in weeks is 7.6. This means that almost 20,000 SAEs that should be observable in the publicly available VAERS Domestic dataset were not present at the time they occurred and were originally reported. This means that only 7,065 (red)/26601 (blue) = ~20% of the actual SAEs as of that date (week 1) were entered into the database.

Only after a lag time of almost 2 months did this data become visible. If week 5 is examined, this lag-time becomes 10 weeks (Figure 8 - right). It is only recently that these data were made visible and this is most likely due to a huge backlog being tended to. The fact that the data sets have converged is due to the backlog being sufficiently dealt with. This phenomenon was found to exist to varying degrees in all AEs checked. Figure 9 shows 3 representative plots for Chills, Death and Breakthrough COVID-19 AEs. It is fortunate (in a way) that the death data does not seem to have been a victim of the lag like some others. This phenomenon was also not dependent on an AE being mild or severe but the degree to which the phenomenon occurred in each AE is yet to be ascertained. This can be checked.

Another way to assess temporal differences in data entry is to calculate the number of days between the onset date (ONSET_DATE)[15] and the date that the AE was input into the VAERS database (TODAY'S_DATE)[16] using only the most recent updated file. For example, the difference between the completed form entry date and the onset of the AE date should be the same for any two

15 Onset Date: The date of the onset of adverse event symptoms associated with the vaccination as recorded in the specified field of the form.

16 Today's date: The date the form was completed.

Figure 8: Shaded plots showing the SAE data as they were input per respective update (grey shaded region) compared with these data as they are reported in each individual updated file (black)

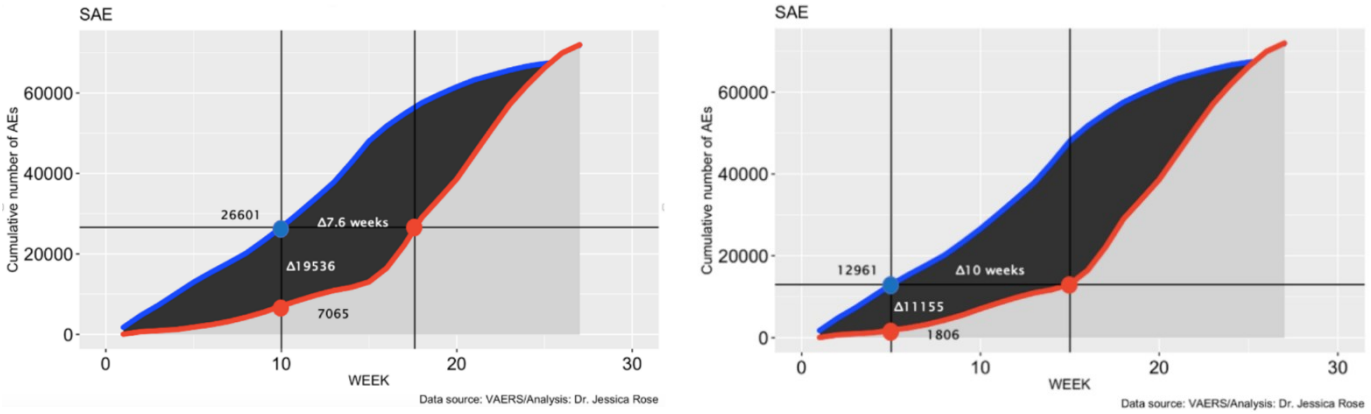
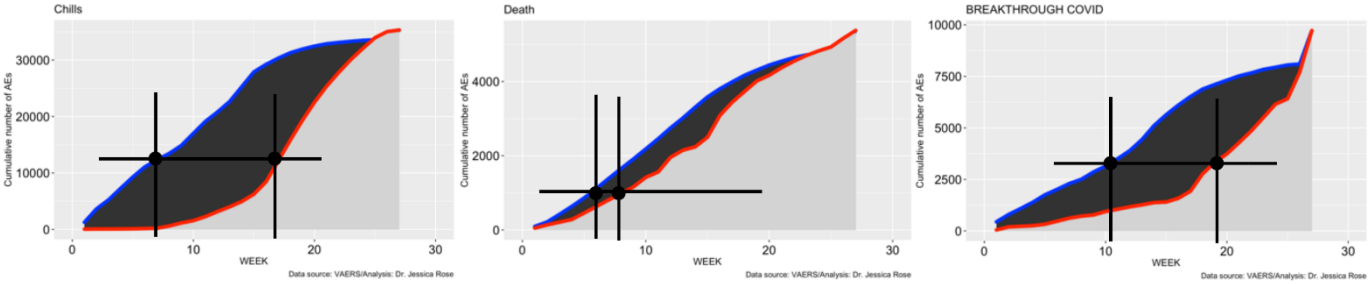


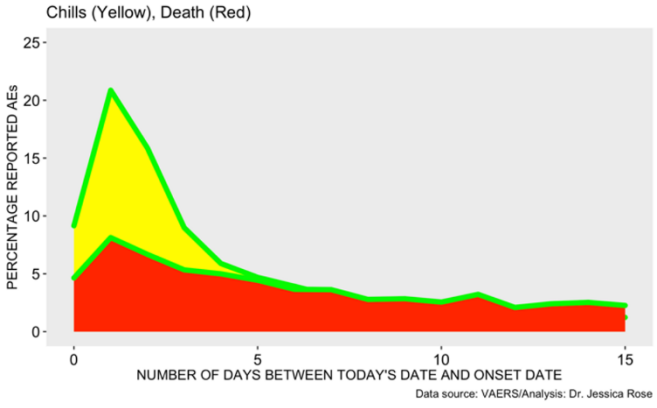
Figure 9: Shaded plots showing the Chills, Death and Breakthrough COVID AE data as they were input per respective update (grey shaded region) compared with these data as they are reported in each individual updated file (black)



randomly selected AEs. If there was a difference between the percentages of reports made for any two AEs, based on the difference between entry date and onset of AE date, then this would require explanation, especially if the difference was statistically significant. The most frequently reported AE in the VAERS system in the context of COVID-19 products is "Chills". I chose this AE as a positive control against deaths in the context of whether or not these two AE types were being added to the publicly available VAERS database in the same way, temporally.

Figure 10 shows the percentages of reported Deaths and Chills as a starting point for the comparison. The T-test confirms a statistically significant difference between the respective means of the Death and Chills AEs with regards to differences

Figure 10: Time series plot showing percentages of Chills (green/yellow) and Death (green/red) of the total VAERS dataset (as of update July 30th, 2021) against the number of days calculated in between the entry date of the report into the database and the onset date of AE for up to 15 days' difference

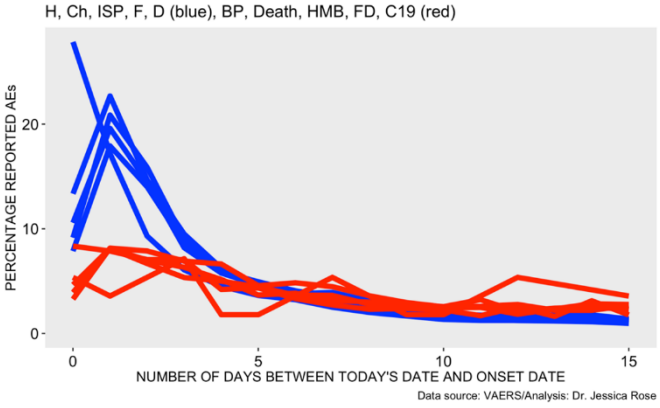


in reporting times following onset of AE with a p-value = 0.005. The figures show areas under the curves generated to demonstrate how many more entries were made in the case of Chills than for Death within the first 5 days following onset of AE.

3.4.2 Lag time dependency on AE type?

Figure 11 shows the percentages of reported Deaths, Bell's palsy, Heavy menstrual bleeding, Myocarditis, Injection site pruritis, Chills, Headache, and Fatigue data against the differences in days between their onset dates and the entry dates into the Domestic front-end VAERS system that is available for download. These 10 were selected since 5 are classified as severe and 5 are classified as mild.

Figure 11: Time series plot showing percentages of reported Headache (H), Chills (Ch), Injection site pruritis (ISP), Fatigue (F), Dizziness (D) (blue), Bell's palsy (BP), Death (D), Heavy menstrual bleeding (HMB), Foetal death (FD), COVID-19 (C19) (red) of the total VAERS dataset (as of update July 30th, 2021) against the number of days calculated in between the entry date of the report and the onset date of AE



There is a clear difference in the percentages of reports made between the mild AEs: Headache (H), Chills (Ch), Injection site pruritis (ISP), Fatigue (F) and Dizziness (D) and severe AEs: Bell's palsy (BP), Death (D), Heavy menstrual bleeding (HMB), Foetal death (FD), COVID-19 (C19). In the case of the mild AEs listed, the area under the curves (AUCs) are greater than the AUCs in the first few days following the onset of the AE. In the cases of the more severe AEs, <10% of reports were entered within the first few days. It is yet unclear whether or not this is a coincidence.

3.5 Are SAEs being downgraded to MAEs each week?

The rate of SAE occurrence according to VAERS data is 19% (nSAE/N reports to VAERS (%)). If we use only Pfizer data, this rate increases to 21%. If we normalize to dose number, we get 0.02% rate of SAE (nSAE/N doses) so this translates to ~1/5000 individuals succumbing to a SAE. There is variation between the criteria that the CDC uses to determine SAEs in VAERS and the medical definition of SAEs [4,5,6,7]. This raises the question of whether specific SAE reports in VAERS are downgraded over time to MAEs. The short answer is no. To determine whether or not SAEs were being downgraded to mild AEs, I semi-joined the datasets for a selected update date

Table 1: Calculated SAE and MAE differences between reference file and original file for 10 sample update files downloaded from VAERS

											Reference Update (RU)	
Δ (date-RU)	03_05_21	03_12_21	03_19_21	03_26_21	04_02_21	04_09_21	04_16_21	04_23_21	04_30_21	05_07_21	05_14_21	**21_05_21**
Δtotal AE count	86	118	105	124	94	94	93	120	162	149	77	0
ΔSAE count	14	38	35	49	23	28	28	53	107	98	49	0
ΔMAE count	72	80	70	75	71	66	65	67	55	51	28	0
Δ% SAE	0	0	0	0	0	0	0	0	0	0	0	0
Δ% MAE	0	0	0	0	0	0	0	0	0	0	0	0

(03/05/21) with 10 sequential updates to maintain the same smaller cohort within the data frames. This allowed the comparison of the original SAE and MAE counts to the original counts for the individual dataframes to check if the counts were changing as updates were being added. None of the SAE counts were different when compared to semi-joined dataframes which means that SAEs are not being downgraded to mild AEs as the updates come in (Table 1). The discrepancies in deltas seen in adverse events (and thus both SAEs and MAEs) are most likely due to variations in data reporting and recording that are known.

4 Discussion

Functioning pharmacovigilance in VAERS was examined in this study. It appears from this short appraisal that although VAERS could be a functioning pharmacovigilance system, it is not being used as such. The only reference to legitimate deletion of data from the VAERS system was in the VAERS/WONDER 'Reporting Issues' section, which claims that 'Duplicate event reports and/or reports determined to be false are removed from VAERS'. Despite this 'disclaimer', there is no way to check or validate 'falseness' of data that may have been removed. This means that, in the case of deleted deaths, which represent 3% of all death data, their removal needs to be explained. These deaths were reported to VAERS and recorded by hired CDC contractors. They represent people who died in temporal proximity to having been given an as-yet non-FDA-approved, experimental transfective biological product by intramuscular injection. They cannot simply be deleted. Something worth noting was the commonality in deleted entries where a causality relationship between the injections and the AE was not only implied but also suggested by the sender, which is typically the physician or emergency-room physician who attended to the individual's case. Refer to Supplementary Table 1 for deleted death entries in the VAERS Wayback machine.

Trained contractor staff are required to enter each VAERS report into the database, and if it should be deemed necessary to delete a VAERS ID from this database once entered, then it must be documented with a valid reason for the deletion. In addition, when a VAERS ID number is changed to a new number, this should also be documented by contractor staff. It has been suggested that vaccine-induced deaths have been classified as COVID-19 deaths. If this is the case, then deaths are being skewed away from the elusive vaccine-induced death count toward the COVID-19 death count [33,34]. It is unscientific to deny any possibility that the injections are the possible cause of the injuries, particularly in some cases where the clear temporal proximity makes this possibility a high probability [8,35]. If this denial was implemented into a system of denial, it would most likely manifest in this way.

VAERS was designed to reveal potential risk signals from data, but if these signals are not detectable as they are received, then they are not useful as timely warnings. There is evidence that the VAERS data are being entered into the publicly available dataset much later than one would expect, considering that this is a passive system. It is conceivable that death AEs have extended processing times for the issuance of death certificates, but there would be no reason for other AEs, severe or mild, to have delays with regards to data entry, especially not delays greater than 4 weeks. Public health policy decisions on expanding the vaccination program might have been made differently if the true rates of reported SAEs and deaths had been known in real time. Similarly, if individuals knew of SAEs and deaths occurring so early on in the rollout, and also that the percentage of SAEs is atypically high, then perhaps they would have exercised their rights to informed consent, declined these injections or simply waited for safety data to come in. This is precisely what the VAERS

system is designed for in its pharmacovigilance task: to warn policy makers and individuals of potential risks not detected during clinical trials. If there is a large backlog of data, then more trained staff need to be hired to expedite data entry to ensure that the VAERS system is able to deliver safety signals as they are reported. In the case where late entry of data occurs due to another reason, then this needs to be acknowledged, investigated and remedied. The evidence provided herein lends to the hypothesis that data is being entered according to AE severity. This alone requires investigation.

As a point of concern with regards to CDC safety signal metrics, as defined in section 2.3.1 in the SOP, the proportional reporting ratio (PRR) is used to define safety signals originating from VAERS. The PRR is a metric that compares the ratio of specific AEs to total AEs for vaccine products. It is defined as:

$$PRR = \frac{\left[\frac{a}{(a+b)}\right]}{\left[\frac{c}{(c+d)}\right]}$$

where a = specific AE for specific vaccine; b = all other AEs for specific vaccine; c = specific AE for all other vaccines; d = all other AEs for all other vaccines [36,37]. However, this technique is inherently flawed in that the PRR does not change when the specific vaccine-related AE event counts are very large or very small [34,36,37,38]. Therefore, the scaling factor that arises due to the excess of specific AEs is normalized to the total number of AEs, and this ratio is then again normalized to the total for all other vaccines. This is a problem in the context of the COVID-19 injectable products since both the specific AEs and the total number of AEs are atypically high. This means that no matter how many times higher the death rate, for example, the PRR will be the same as it would be for a product that was not killing people at all. The PRR, therefore, on its own, cannot be used as reliable a safety signal detection metric – it does not work.

To be clear, the absolute number of AEs reported in the context of the COVID-19 products is approximately 11x higher than for all the reported AEs for 2020 combined. The absolute number of deaths reported is approximately 42x higher than for all deaths reported for 2020. However, the PRR does not emit a safety signal even though the number of deaths is 266 times higher in the context of the COVID-19 products when compared to INFLUENZA products [32]. In spite of peer-reviewed studies noting significant association of COVID-19 injectable products with Bell's palsy, thrombocytopenia and myocarditis [39,40,41,42], the CDC maintains the position that no specific safety concerns have been identified with regards to SAEs [8,31,43,44,45]. In a recent CDC report titled 'Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events: Pfizer-BioNTech COVID-19 Vaccine' [44], only the severity of the most frequently reported AEs in the VAERS database are reported in tabular form and not the SAEs themselves. They report that occurrence of SAEs involving system organ classes and specific preferred terms were balanced between vaccine and placebo groups and presented at a mere 0.5%, and although SAEs (grade ≥3, defined as interfering with daily activity) occurred more commonly in vaccine recipients than in placebo recipients, their claim is that no specific safety concerns were identified with regards to SAEs, which is false [43,44,45].

One more discussion point that is worth its own publication but will be added as a point of interest in this study is the Under-Reporting Factor (URF) of AEs. Under-reporting is a problem in pharmacovigilance systems, VAERS included. VAERS is a passive reporting system, and it has been suggested as part of a Harvard study that a mere 1% of AEs are reported to VAERS [46]. However, this is not necessarily the case, nor is it

universally applicable for all products; certainly not for distinct AEs. For example, under-reporting of mild AEs such as rashes or low-grade fever would most likely be far greater than for SAEs, such as death. To calculate the URF, the expected number of SAEs (E_{SAE}) is divided by the observed number of SAEs (O_{SAE}). The E_{SAE} is calculated by multiplying the total number of doses administered in the U.S. (assuming a single dose can result in an AE) by the number of SAEs recorded in COVID-19 product safety trials. According to the FDA Safety Overview of the Pfizer/BioNTech COVID-19 product (Study C4591001 – refer to section 5.2.6 page 33) [47,48]. 0.7% of Pfizer/BioNTech COVID-19 product recipients suffered SAEs. As of August 10th, 2021, 197,399,471 million Pfizer/BioNTech COVID-19 product doses had been administered in the U.S. [49,50] and therefore the number of expected SAE occurrences in the U.S. volunteer recipients of the Pfizer/BioNTech products should be ~1.4 million SAEs, if we use this reported rate. Thus, the ratio of E_{SAE} to O_{SAE} is 31 to 1, suggesting a URF of 31 ($N_{SAE\_Pfizer\_trial}/N_{SAE\_Pfizer\_VAERS}$ = ~1.4M/43,948). Using this URF for all VAERS-classified SAEs, estimates to date are as follows: 205,809 dead, 818,462 hospitalizations, 1,830,891 ER visits, 230,113 life-threatening events, 212,691 disabled and 7,998 birth defects to date [38]. Since the URF for MAEs is very likely larger than for SAEs, it is satisfactory to assume that 31 is a humble estimate URF for all AEs (refer to Supplementary Table 2). Relative reporting rates are also shown in Supplementary Table 2 to demonstrate that that AE reports associated with COVID-19 products are much higher than for previous years. For all symptoms listed in red, we limited the search to 20–60-year-olds since these people are less noisy with respect to symptoms and younger people aren't yet vaccinated. All fields color-coded yellow contain observed/expected incidence rates >100, and these only occur in the non-control AEs, such as reported AEs that are presumably unrelated to the vaccines, like 'Lyme disease', seen in blue and green in Supplementary Table 2.

5 Conclusion

It cannot be stressed enough when referring to VAERS data collected in the context of the COVID-19 injectable products that effective antiviral responses against the nCoV-2019 virus in the form of both cellular and humoral immune responses have been reported in peer-reviewed studies [51–56]. Because of the low Infection Fatality Rate, indicating effective and robust immune responses, it remains unclear why multiple experimental mRNA vaccines have been fast-tracked through conventional testing protocols and are also being fast-tracked through production and administration into the public. With repurposed drugs like hydroxychloroquine and Ivermectin showing extremely positive results in patients [57–68], it is also unclear why these drugs are not being more extensively promoted as effective tools in the fight against this virus. What is clear is that the injectable products are proving unsafe for many individuals and inefficacious in others (see Israeli data in Supplementary Material). As part of the WHO's own minimum requirements for a functioning pharmacovigilance system, sub-standard products need to be removed from circulation to ensure patient safety. Since VAERS is capable as a functioning pharmacovigilance system as it reveals safety issues with the COVID-19 biologicals, it should be used as such, but it is not.

Despite the low frequency of missing VAERS IDs, data have been deleted from the VAERS database, and this requires explanation, not only ethically but also because it lends to the possibility of inexact measurements of death counts and therefore can potentially lead to missed signals. Statistical power is primarily influenced by sample size (also effect size and significance level), and the

bigger the sample size, the higher the statistical power. The deleted data from the total VAERS ID count are individuals enrolled in post-market surveillance human-subject studies: the whereabouts of their VAERS reports of death need to be accounted for. There is absolutely no reason for these data to be missing, from what can be ascertained. If the data were false, as was suggested as the only reason to delete an entry, then there needs to be a record of this edited data made available with the publicly available VAERS data.

Data are being retroactively added to the VAERS database far later than would be expected for the system to be considered a timely, functioning pharmacovigilance system. This could be explained by manual curation of a large backlog of data. However, if AEs are being entered differentially, with respect to time, based on severity, then we all must ask the difficult question: "Why?" Again, VAERS was designed to reveal potential risk signals from data, but if these signals are not detectable as they are received, then they are not useful as warnings and pharmacovigilance becomes moot. The duration between reporting following onset of an adverse event reaction and recording into the VAERS publicly available data varies from a few days to many months. If earlier information was available to public health policy-makers and to the public, including the off-the-charts prevalence of SAEs (19%) and deaths, then perhaps the decision to volunteer to have these products injected would have been more prevalently declined or simply put on hold until more safety data had accumulated. This, again, is part of pharmacovigilance that has failed with regards to assessment of risk/benefit management.

According to this analysis, VAERS IDs are not being downgraded from SAEs to mild AEs. In fact, the percentage of SAEs continue to increase from month to month. Even without considering the URF, the ratio of fully vaccinated individuals succumbing to an adverse event is high. With approximately 1 in every 400 individuals experiencing an adverse event (~1 in every 25,000 for death) in the context of the COVID-19 fully vaccinated population in the United States, it is therefore unclear why these injections are continuing to be used in the human population, especially since no long-term effects are known and no long-term data exists, to date. It was important to contextualize death counts since a disproportionate number of all the missing data AEs are deaths.

It may appear that the number of missing VAERS IDs is nothing to be concerned about from an analytical point of view, but I remind the reader that these are not just data: they are people. This report addressed three issues that respond to the question of VAERS pharmacovigilance by analyzing VAERS data in relation to: 1. deleted reports, 2. delayed entry of reports, and 3. recoding of MedDRA terms from severe to mild.

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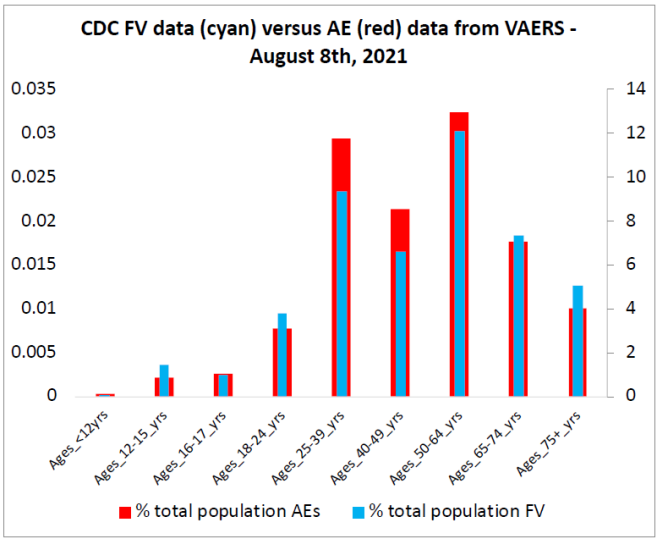
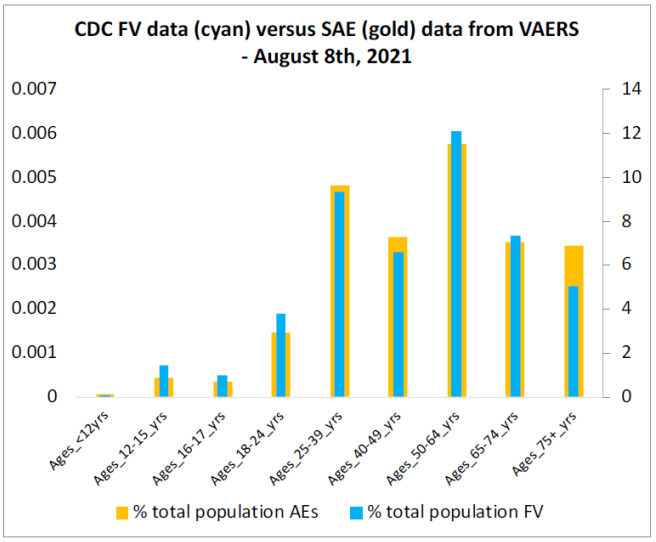
7 Supplementary Materials

Supplementary Figure 1: Injection rates in each age group in the general population compared to the total AE VAERS reports (above) and total SAE VAERS reports (below)





Supplementary Table 1: The true deletions shown in the context of all missing data. The new VAERS IDs assigned to the redundant entries are also shown.

Count	VAERS ID missing	New VAERS ID	True deletions	DIED classification (B&A)	Adverse Event	Deleted from date
1	918723	N	TRUE	Y(Location: foreign)	Death	1/7/21
2	923149	N	TRUE	Y(Location: foreign)	Death	1/7/21
3	930386	N	TRUE	Y	Death	1/15/21
4	930418	N	TRUE	Y	Death	1/15/21
5	934963	N	TRUE	Y	Death	1/15/21
6	937985	N	TRUE	Y(Location: foreign)	Death	1/15/21
7	940950	N	TRUE	Y	Death	1/15/21
8	940954	930466	NA	Y/Y	Death	1/15/21
9	944273	N	TRUE	Y	Death	1/15/21
10	944385	N	TRUE	Y	Death	1/22/21
11	944659	944641	TRUE	Y/Y	Death	1/15/21
12	946097	935767	NA	Y/Y	Death	1/15/21
13	947974	940955	NA	Y/Y	Death	1/22/21
14	949547	945253	NA	Y/Y	Death	1/22/21
15	951960	985715	NA	Y/Y	Death	1/29/21
16	955878	N	TRUE	Y	Death	1/22/21
17	957321	N	TRUE	Y(Location: foreign)	Death	6/11/21
18	960437	N	TRUE	Y	Death	1/22/21
19	964729	1329449	NA	Y/NA	Death	1/29/21
20	964956	962940	NA	Y/Y	Death	1/29/21
21	966236	Dead in 30 mins	TRUE	Y	Death	1/29/21
22	970044	950533	NA	Y/NA	Death	1/29/21
23	970139	950441	NA	Y/Y	Death	1/29/21
24	970161	ITP?	TRUE	Y	Death	1/29/21
25	971561	962325	NA	Y/Y	Death	1/29/21
26	971800	921768	NA	Y/Y	Death	1/29/21
27	978872	971969	NA	Y/Y	Death	2/4/21
28	982778	935815	NA	Y/Y	Death	1/29/21
29	983482	978959	NA	Y	Death	2/4/21
30	999818	N	TRUE	Y(Location: foreign)	Death	2/12/21
31	1000669	986901	NA	Y/Y	Death	2/4/21
32	1000910	977186	NA	Error: Wrong Patient (documentation in EMR)	Unevaluable	2/4/21
33	1004651	N	TRUE	Y	Death	2/18/21
34	1011588	985527	NA	Y/NA	Death	2/18/21
35	1017127	989006	NA	Y/Y	Death	2/12/21
36	1020144	994544	NA	Y/Y	Death	2/12/21
37	1024103	N	TRUE	Y	No death	2/12/21
38	1024731	1024592	NA	Y/Y	Death	2/12/21
39	1045540	939050	NA	Y/Y	Death	4/1/21
40	1048687	N	TRUE	Y	Cerebrovascular Accident	3/5/21
41	1051447	Litigation request	TRUE	Y	Death	3/11/21
42	1064933		TRUE	Y(Location: foreign)	Death	8/6/21
43	1074247	N	TRUE	Y	Death (2 y/o)	4/1/21
44	1076914	N	TRUE	Y	Death	3/19/21
45	1102077	1090801	NA	Y/Y	Death	3/19/21
46	1108447	1145662? (JJ?P?)	NA	Y/Y	Death	4/1/21
47	1108969	1096497	NA	Y/Y	Death	3/19/21
48	1113963	1084036	NA	Y/Y	SARS-CoV-2	3/19/21
49	1122171	1084419/1126060	NA	Y/Y	Death	4/1/21
50	1131199	1037207	NA	Y/Y	Death	4/1/21

51	1131598	N	TRUE	Y	Death	4/16/21
52	1131608	1123165	NA	Y/Y	Death	4/16/21
53	1133045	1059857	NA	Y/NA	Death	4/8/21
54	1137741	N	TRUE	Y	ARDS	4/1/21
55	1153083	1134651	NA	Y/Y	Cerebrovascular accident	4/1/21
56	1153539	1120952	NA	Y/Y	Death	4/8/21
57	1155507	N	TRUE	Y	Death	4/1/21
58	1157502	1098028	NA	Y/Y	Death	4/1/21
59	1161844		TRUE	Y(Location: foreign)	Death	7/30/21
60	1162016	N	TRUE	Y	Death	4/16/21
61	1176029	940955	NA	Y/Y	Death	4/8/21
62	1179211	N	TRUE	Y	Death	4/8/21
63	1182768	1145183	NA	Y/Y	Death	4/8/21
64	1203204	1191979	NA	Y/Y	Death	4/16/21
65	1203633	1169518	NA	Y/Y	Death	4/16/21
66	1205852	1145526	NA	Y/Y	Death	4/16/21
67	1205973	1120315	NA	Y/NA	Death	4/16/21
68	1207253	1281778	NA	Y/Y	Death	4/16/21
69	1207999	1147303	NA	Y/Y	Death (Changed 2x)	6/11/21
70	1208299	N	TRUE	Y	Death	4/16/21
71	1209810	N	TRUE	Y	Death	4/23/21
72	1209975	1027051	NA	Y/Y	Death	4/23/21
73	1210750	1207989	NA	Y/Y	Death	4/16/21
74	1212517	1205423	NA	Y/Y	Death	4/23/21
75	1212701	230404	NA	Y/Y	Death	4/23/21
76	1213488	1122080	NA	Y/Y	Death	4/16/21
77	1215091	N	TRUE	Y	Death	4/16/21
78	1216074	?	TRUE	Y	Death	4/23/21
79	1218081	1199455	NA	Y/Y	Death	4/23/21
80	1218343	?	TRUE	Y	Death	4/30/21
81	1218740	N	TRUE	Y	Death	4/23/21
82	1219137	1171204	NA	Y/Y	Death	4/23/21
83	1219153	N	TRUE	Y	Death	4/23/21
84	1219898	N	TRUE	Y	Death	4/23/21
85	1220310	1033682	NA	Y/Y	Death	4/23/21
86	1221164	1221163	NA	Y/Y	Death	4/23/21
87	1223602	1039271	NA	Y/Y	Death	4/23/21
88	1223603	1044825	NA	Y/NA	Death	4/23/21
89	1223695	1104671	NA	Y/Y	Death	4/23/21
90	1227272	1202320?	NA	Y/Y	Death	5/21/21
91	1227283	1160365	NA	Y/Y	Death	4/23/21
92	1228634	1101703	NA	Y/NA	Death	4/23/21
93	1229325	N	TRUE	Y	Death	4/23/21
94	1229793	N	TRUE	Y	Death	4/23/21
95	1230023	1214079	NA	Y/NA	Death	4/23/21
96	1231377	?	TRUE	Y	Death	4/23/21
97	1232040	1116557	NA	unk	Not Death	4/23/21
98	1233431	1126563	NA	Y/Y	Death (Changed 2x)	6/11/21
99	1235812	N	TRUE	Y	Death	4/23/21
100	1235826	1199575	NA	Y/Y	Death	4/23/21

Supplementary Table 1 continued

101	1237250	N	TRUE	Y	Death	4/23/21
102	1237773	1224121	NA	Y/Y	Death	4/23/21
103	1241174	N	TRUE	Y	Death (Changed 2x)	6/11/21
104	1242693	1198211	NA	Y/Y	Death	4/23/21
105	1242935	1137886	NA	Y/NA	Death	4/23/21
106	1243057	1230389	NA	Y/Y	Death	4/23/21
107	1243311	1230587	NA	Y/NA	Death	6/25/21
108	1243516	1225942	NA	Y/Y	Death(16y/o)	4/23/21
109	1244328	1199143/1363773?	NA	Y/Y	Death	4/23/21
110	1246186	N	TRUE	Y	Death	4/30/21
111	1246844	1203534?	NA	Y/Y	Death	4/30/21
112	1247482	1203475	NA	Y/Y	Death	4/30/21
113	1248103	N	TRUE	Y	Death	4/30/21
114	1249552	1000968	NA	Y/NA	Death	6/25/21
115	1250965	N	TRUE	Y	Death	4/30/21
116	1255689	N	NA	Y	Death	6/25/21
117	1255745	N	TRUE	Y	Death (2 y/o)	4/30/21
118	1261822	1155002?	NA	unk	Diabetes mellitus	4/30/21
119	1262644	1168198	NA	Y/Y	Death	4/30/21
120	1263917	?	TRUE	Y	Death	4/30/21
121	1266028	N	TRUE	Y	Death (Changed 2X)	6/25/21
122	1266783	1196113	NA	Y/NA	Death	4/30/21
123	1270090	1217275	NA	Y/NA	Death	4/30/21
124	1270235	1270229	NA	Y/NA	Death	4/30/21
125	1270697	1112773	NA	Y/Y	Death	4/30/21
126	1271195	1176003	NA	Y/Y	Death	4/30/21
127	1271332	1123229	NA	Y/Y	Death	4/30/21
128	1271352	1208360	NA	Y/Y	Death	4/30/21
129	1271604	N	TRUE	Y	Death	4/30/21
130	1271889	1025171	NA	Y/NA	Death	4/30/21
131	1276250	N	TRUE	Y	Death (Changed 1x)	5/21/21
132	1279436		TRUE	Y	Death (Changed 1X)	7/16/21
133	1282687	N	TRUE	Y	Death (Changed 1x)	6/25/21
134	1284326		TRUE	Y(Location: foreign)	Death	7/16/21
135	1284667	1401679	NA	unk/Y	Adverse event	5/7/21
136	1288451	N	TRUE	Y	Death	5/21/21
137	1292382	1230371	NA	Y/Y	Death	5/7/21
138	1292417	1124195	NA	Y/Y	Death	5/7/21
139	1293310	1291385	NA	Y/Y	Death	5/7/21
140	1293571	N	TRUE	Y	Death (Changed 1x)	7/2/21
141	1293685	N	TRUE	Y	Death	5/7/21
142	1313571	1311248	NA	Y/NA	Death	5/14/21
143	1323317	1286108	NA	Y/Y	Death	7/2/21
144	1327681	1327666	NA	Y/Y	Death	5/21/21
145	1329956	1291811	NA	Y/Y	Death	5/21/21
146	1330375	1213047	NA	Y/Y	Death	5/21/21
147	1330653	N	TRUE	Y	Death	5/21/21
148	1331099	N	TRUE	Y	Death	5/21/21
149	1332457	N	TRUE	Y	Death	5/21/21
150	1334003	1297262	NA	Y/Y	Death	5/21/21

Supplementary Table 1 continued

151	1334181	1282119	NA	unk/NA	Adenovirus test	5/21/21
152	1334269	1334263	NA	Y/NA	Death	5/21/21
153	1334696	N	TRUE	Y	Death	5/21/21
154	1334875	1175722	NA	Y/Y	Death	5/21/21
155	1336138	1302428	NA	Y/Y	Death	5/21/21
156	1338402	N	TRUE	Y	Death	6/4/21
157	1338586	N	TRUE	Y	Death	6/25/21
158	1345049	military	TRUE	Y	Death	7/23/21
159	1345689	1161963	NA	Y/Y	Death	6/4/21
160	1349013		TRUE	Y	Death	7/30/21
161	1349598	1307657	NA	Y/Y	Death/Suicide (17 y/o)	6/4/21
162	1351033	N	TRUE	Y	Death	6/11/21
163	1353097	N	TRUE	Y	Death (15 y/o botch job)	6/11/21
164	1355181	951678	NA	Y/Y	Death	6/4/21
165	1357031	1311693	NA	Unk/Y	Bone biopsy	6/4/21
166	1357033	12922137	NA	Y/Y	Death	6/4/21
167	1363909	1326951	NA	Y/Y	Death	6/4/21
168	1367961	1271213	NA	Y/Y	Death	6/4/21
169	1369944	N	TRUE	Y	Death	6/4/21
170	1371376	1356045	NA	Y/Y	Death	6/4/21
171	1371898	N	TRUE	Y	Death	6/4/21
172	1372095	N	TRUE	Y	Death	6/4/21
173	1372291	1371905	NA	Y/Y	Death	6/4/21
174	1373818	1355806	NA	Y/Y	Death	6/4/21
175	1374141		TRUE	Y	Death	8/6/21
176	1383620	1382906	NA	Y/Y	Death (15 y/o)	6/11/21
177	1384697		TRUE	Y(Location: foreign)	Death	7/16/21
178	1391003		TRUE	Y(Location: foreign)	Death	7/16/21
179	1396407	1394314	NA	Y	Death	7/30/21
180	1409720	1385038	NA	Y/Y	Death	6/25/21
181	1412023		TRUE	Y(Location: foreign)	Death	7/16/21
182	1412025		TRUE	Y(Location: foreign)	Death	7/30/21
183	1412027		TRUE	Y(Location: foreign)	Death	7/30/21
184	1412492	1209873	NA	Y/Y	Death	7/16/21
185	1414996		TRUE	Y	Death	7/23/21
186	1416375	N	TRUE	Y(Location: foreign)	Death	7/9/21
187	1419174	N	TRUE	Y(Location: foreign)	Death (foetus – no data)	7/2/21
188	1420738	1154465	NA	Y/Y	Death (MS)	7/2/21
189	1423098	1381906	NA	Y/Y	Death	7/16/21
190	1425803	1108312	NA	Y/Y	Death (JJ)	7/2/21
191	1425809	1296197	NA	Y/Y	Death (JJ:1805018)	7/2/21
192	1425810	1396485	NA	Y/Y	Death (JJ:1805018)	7/2/21
193	1425811	1396378	NA	Y/Y	Death (JJ:1805018)	7/2/21
194	1426491	1437355	NA	Y/Y	Death (JJ:1805018)	7/2/21
195	1426828	1386841	NA	Y/Y	Death (JJ:1805018)	7/2/21
196	1426983	1355185	NA	Y/Y	Death (JJ:1805018)	7/2/21
197	1427916		TRUE	Y	Death	7/16/21
198	1428844	N	TRUE	Y(Location: foreign)	Death	7/9/21
199	1428951		TRUE	Y(Location: foreign)	Death	8/6/21
200	1429457	1406840	NA	Y	Death (13y/o/myo/2nd shot)	7/23/21
201	1432771		TRUE	Y	Death	7/16/21
202	1435280	N	TRUE	Y(Location: foreign)	Death	7/9/21
203	1435440		TRUE	Y(Location: foreign)	Death	7/30/21
204	1435941	Causation susp	NA	Y	Death/Myo	7/23/21
205	1437520	1338618?	NA	Y	Death	7/23/21
206	1437660		NA	Y	Death	7/16/21
207	1440209	1285387	NA	Y/Y	Death	7/16/21
208	1440557		TRUE	Y	Death	7/23/21
209	1442083		TRUE	Y(Location: foreign)	Death	7/30/21
210	1442096		TRUE	Y(Location: foreign)	Death	7/30/21
211	1445472		TRUE	Y(Location: foreign)	Death	7/30/21
212	1445472		TRUE	Y(Location: foreign)	Death	7/30/21
213	1450091	1381906	NA	Y/Y	Death	7/16/21
214	1450342		TRUE	Y	Death	7/30/21

Supplementary Table 1 continued

Supplementary Table 2: Table using Under-Reporting Factor (URF) conversion (30x) to demonstrate suggested actual numbers of AEs rather than simply reported values in VAERS.
Data source: VAERS/Analysis: Steve Kirsch, Dr. Jessica Rose

Adverse Event (AE)	Observed AE 2021 (N)	Number AE (2015-2019)	Expected (Average/year)	Incidence Rate (AE) (N/Average per year)	URF adjusted (OBS*31)
Metal poisoning	2.0	47.0	9.4	0.2	62.0
Otitis media	48.0	255.0	51.0	0.9	1,488.0
Hepatitis	331.0	1,457.0	291.4	1.1	10,261.0
Bursitis	189.0	395.0	79.0	2.4	5,859.0
Conjunctivitis	172.0	278.0	55.6	3.1	5,332.0
Caesarean section	38.0	97.0	19.4	2.0	1,178.0
Wart	1.0	7.0	1.4	0.7	31.0
Rotator cuff syndrome	55.0	148.0	29.6	1.9	1,705.0
Breech delivery	0.0	3.0	0.6	0.0	0.0
Cancer	31.0	132.0	26.4	1.2	961.0
Diabetes	155.0	284.0	56.8	2.7	4,805.0
Obesity	14.0	9.0	1.8	7.8	434.0
Lyme disease	42.0	53.0	10.6	4.0	1,302.0
Abortion Spontaneous	707.0	90.0	18.0	39.3	21,917.0
Anaphylactic Reaction	1,503.0	204.0	40.8	36.8	46,593.0
Aphasia (inability to talk)	1,184.0	55.0	11.0	107.6	36,704.0
Appendicitis	433.0	11.0	2.2	196.8	13,423.0
Bell's Palsy	2,637.0	133.0	26.6	99.1	81,747.0
Blindness	723.0	86.0	17.2	42.0	22,413.0
Cardiac arrest	719.0	14.0	2.8	256.8	22,289.0
Chills	61,972.0	4,725.0	945.0	65.6	1,921,132.0
Cough	9,637.0	1,002.0	200.4	48.1	298,747.0
Deafness	1,022.0	117.0	23.4	43.7	31,682.0
Death	6,639.0	90.0	18.0	368.8	205,809.0
Deep vein thrombosis	1,473.0	14.0	2.8	526.1	45,663.0
Depression	503.0	488.0	97.6	5.2	15,593.0
Diarrhoea	13,495.0	6,262.0	1,252.4	10.8	418,345.0
Dyspnoea (difficulty breathing)	20,674.0	194.0	38.8	532.8	640,894.0
Dysstasia (difficulty standing)	1,349.0	133.0	26.6	50.7	41,819.0
Fatigue	61,900.0	4,575.0	915.0	67.7	1,918,900.0
Guillain-Barre syndrome (GBS)	448.0	378.0	75.6	5.9	13,888.0
Headache	73,565.0	6,231.0	1,246.2	59.0	2,280,515.0
Herpes zoster	4,807.0	700.0	140.0	34.3	149,017.0
Insulin resistance	6.0	6.0	1.2	5.0	186.0
Multiple organ dysfunction syndrome	26.0	37.0	7.4	3.5	806.0
Myalgia	17,047.0	3,208.0	641.6	26.6	528,457.0
Myocarditis	671.0	73.0	14.6	46.0	20,801.0
Neuropathy	133.0	195.0	39.0	3.4	4,123.0
Paraesthesia	9,860.0	2,440.0	488.0	20.2	305,660.0
Paralysis	179.0	411.0	82.2	2.2	5,549.0
Parkinson's disease	26.0	5.0	1.0	26.0	806.0
Pericarditis	447.0	49.0	9.8	45.6	13,857.0
Pruritus	18,103.0	11,250.0	2,250.0	8.0	561,193.0
Pulmonary embolism	1,191.0	10.0	2.0	595.5	36,921.0
Seizure	2,362.0	431.0	86.2	27.4	73,222.0
Completed suicide	19.0	3.0	0.6	31.7	589.0
Thrombosis	1,588.0	45.0	9.0	176.4	49,228.0
Tinnitus	6,523.0	282.0	56.4	115.7	202,213.0
Total	**324,649.0**	**47,112.0**	**9,422.4**	**3,758.3**	**10,064,119.0**

Unrelated events (blue): The goal for symptoms like metal poisoning, hepatitis, and otitis media (shown in blue) is to look for the propensity to over-report this year. If this was just over reporting we'd see a rate increase for these symptoms that are unrelated to the vaccines and are not comorbidities.
Pre-existing comorbidities (green): These conditions like diabetes and cancer in the table above increase simply because of the increased number of people filing reports in 2021.
Symptoms: For all symptoms (Deaths and others), we limited the search to 20-60-year-olds since these people are less noisy with respect to symptoms and younger people aren't yet vaccinated [21].

Supplementary Table 3: Table showing injected versus un-injected individuals in the context of hospitalizations in Israel. Chart courtesy of Dr. Rafael Zioni. Data source: Israel Ministry of Health.

Israel Confirmed Cases, July 4th – July 10th, Vaccinated* vs. Unvaccinated**				
Age Group	Cases, Vaccinated	Cases, Unvaccinated	Percent of Cases Vaccinated	Percent of Population*** Vaccinated
20-29	217	61	78%	77%
30-39	248	84	75%	82%
40-49	356	54	87%	85%
50-59	237	26	90%	89%
60-69	227	14	94%	91%
70-79	143	12	92%	95%
80-89	42	6	88%	91%
קבוצת גיל	נדבקים מחוסנים	נדבקים לא מחוסנים	אחוז נדבקים מחוסנים	אחוז מחוסנים באוכלוסיה
ישראל, מקרי קורונה מאומתים, 4 ביולי עד 10 ביולי, מחוסנים לעומת לא מחוסנים				

Source: Israel Ministry of Health Dashboard
https://datadashboard.health.gov.il/COVID-19/general
** Vaccinated – 2 shots.*
*** Unvaccinated – No shots.*
**** Excluding population with 1 shot.*

8 Author statement

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